16 August 1965

TO: List (AERL personnel + A.R.Kantrowitz)

FROM: W. J. Mowbray (AERL)

SUBJECT: Summary of Contract PH43-66-7, "Studies Basic to Consideration of Artificial Heart Research and Development Program", National Institutes of Health

For your information and compliance, please be advised that we have received Contract PH43-66-7. The period of performance for this program is seven (7) months commencing 13 August 1965. Note, however, that the draft of the final report is due within six (6) months of 13 August 1965. Funds are provided in the amount of $86,372 (estimated cost $80,122 plus fixed fee of $6,250).

Pertinent information has been extracted from the contract and is set forth below:

Article I - Description of Work (Applies to all Tasks)

A. Independently and not as an agent of the Government, the Contractor will furnish all necessary labor, materials and facilities and will exert its best efforts to plan, staff, manage, direct and control conceptual phase study program. In the performance hereof, the contractor shall:

a. Outline the scope of work and functional flows required to resolve possible critical areas of research, development, manufacture, test, training, operations and facilities that may require special effort during the subsequent definition phase.

b. Outline the manner in which the technical approaches to research and development are proposed.

c. Prepare a program plan for both the definition and acquisitionphases which summarizes the total system integration and interface problems and controls, outlines the approach to be used in integrating and relating time, cost and performance factors; outlines systemfunctional analysis reliability, and maintainability.

The Contractor shall conduct investigations, analyze and study the following specific tasks.

Task No. 1 - Assessment and definition of the problem:

MAIMONIDES SUBTASKS 1.3 + 1.4

Assess the mortality and morbidity rates of the entire heart disease population group with special emphasis on a detailed characterization of the immediate cause of death or incapacity including the various physiological, anatomical and cardiological bases of the problem. The study takes into account the immediate problem -- the failure of the blood pump; also new problems resulting from use of artificial organs and concurrent disease which will affect morbidity and mortality either immediately or after installation, and associated and resulting problems which likewise affect mortality and morbidity either immediately or after installation. Thus this study will assess the need for substitution therapy taking into consideration the duration and magnitude of benefit. The results of this

study must be easily usable to determine to what extent the various devices (e.g., artificial valves, pacemakers, temporary ventricular-assist devices and totally implantable artificial hearts) are capable of alleviating the problem taking into account how many will be benefited, for how long, and to what extent, considering not only the above concomitant, related, and resultant factors, but also considering the patient's location in relation to the probable site for implantation and the time available for treatment. The results will also indicate the overall impact on the public health picture as regards to optimal rehabilitation of the patient, the medical and surgical complications which might be expected including the economic factors resulting from such complications, such as the need for continued institutionalization, dependency on professional care, and the servicing requirements. The report resulting from this task shall contain material which will allow the Government to determine which of the artificial heart family of devices, if adequately developed, would have the greatest benefit upon the overall public health problem all factors considered.

Task No. 2 - Characterization of the biomedical and technological problems:

MAIMONIDES SUBTASKS 2.1 + 2.4

Determine the biomedical and technological problems involved with the development of (1) a temporary ventricular-assist device, and (2) a more permanent totally implantable artificial heart. In determining these functional requirements, all of the involved technologies and interfaces will be considered including those involving support, evaluation, and performance. Some of these technologies include physiology, cardiology, anatomy, hematology, surgery, fluid mechanics, reliability, and durability, engineering, and thermodynamics. This task must not only take into account the functional requirements but other problems as well such as the emotional or psychological, the religious, ethical, moral, legal, and economic problems. It must consider the reaction of the patient's family, employer, associates on the job, insurance companies, legal responsibility (i.e., driver licensing, etc.).

Task No. 3 - Technology survey and reference data compilation:

MAIMONIDES SUBTASKS 3.8, 3.9, 3.10

Survey all of the technologies potentially applicable to the artificial heart devices. A thorough description and analysis of each of the subsystems will be made including the energy source, the activator or energy conversion unit, the actual blood pump with its components such as valves, materials, etc., and the control mechanism, etc. Not only must the hardware subsystems be considered in this survey but also other technologies such as medical diagnostic instrumentation, surgical instrumentation, distribution, mechanisms for early detection of impending component failure, etc., must also be described and analyzed. This survey must not only consider existing capabilities in these technologies, but also those readily and predictably available through new designed, techniques, materials, and combinations of techniques in existence currently. This survey must include a review of published literature, present and past activities in the artificial heart and other technological fields, and must include other fact finding (beyond published literature) which is necessary in an adequate and complete assessment and appraisal of technologies. The product of this task must include a summary of the state of the art in each technological area which is potentially applicable to artificial hearts, a comprehensive bibliography of reference data for each with selected abstracts involving key decisions.

Task No. 4 - Estimated future extension of technology:
MAIMONIDES SUBTASKS 4.8, 4.9, 4.10

Analyze the technological advances which might be expected to occur in each of the areas surveyed in Task No. 3. This study will be based on the advances which would be expected to occur within the next 10 years independent of specific artificial heart research and development. The study shall be documented by reference data, and analyses. The final report on this task should "foresee" the state of the art in the development phase, identify weak or soft areas within the technologies, and also predict the state of the art in the more distant future for the purpose of allowing for retro-fit, etc.

Task No. 5 - Determination of key technical problems in artificial heart development: MAIMONIDES SUBTASKS 5.8, 5.9, 5.10

Compare the technological requirements with the current state of the art and the expected future state of the art. As a result of this comparison, identify technological areas requiring futhre extension.

Task No. 6 - Assessment of other resources for artificial heart development: MAIMONIDES SUBTASK 6.4

Identy, assess and evaluate all resources such as research, development, production, installation, maintenance, etc., potentially required, applicable and/or available to artificial heart needs. The product of this task will not only identify these resources but also, as a result of the assessment, identify areas requiring modification, adjustment, extension, or advancement within these resources.

Task No. 7 - Determination of performance criteria for the artificial heart: MAIMONIDES SUBTASKS 7.1 + 7.4

Define, analyze and evaluate the performance criteria. These performance criteria will include patient requirements (e.g., physical, emotional, convenience, etc.) costs, personnel and other resources (including methods, skills, techniques, tools, procedures, etc.) as may be useful in evaluating artificial heart performance.

B. All work under this contract shall be performed under the general guidance and direction of the Project Officer whose position is defined in Article IV. Such guidance and direction shall not, however, effect any change in the cost structure of this contract, increase its estimated cost, or extend the period of performance. Such changes shall be made only by action of the Contracting Officer.

C. The Contractor shall submit interim and final reports as set forth below. These reports shall document and summarize the results of each task study and the final report shall be a correlation of the entire contract studies.

(1) Interim Reports: Monthly progress reports will be required which will clearly indicate the relation of progress to date with that of the program as outlined in A. 1 above. In lieu of the second monthly progress report, the Contractor will submit a report summarizing work to date and updated program for the remainder of the contract period. This report will be made to the Government and to any advisors whom it wishes to have available. An evaluation of progress to date will be made.

(2) Tasks Completion Reports: Twenty (20) copies and one (1) reproducible of a completion report for each task shall be provided to the Government at the completion of such task.

(3) Final Report: The product of these 7 tasks will be consolidated into a report which evaluates and inter-relates the individual findings and provides a solid basis for decisions on the nature, scope, pacing and magnitude of the artificial heart development program. This report will include findings, conclusions, and recommendations for future R&D work. It will include necessary graphs and tables to clarify the narrative and a complete bibliography and selective abstracts involving key decisions. A draft and five copies of this report will be delivered to the Government for approval within 6 months of the starting date of the contract. Fifty (50) copies and a reproducible of the approved report will be delivered.